

Form PTO-1390
(REV 12-29-99)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

1619.0020001/SRL/TBB

U.S. APPLICATION NO. (IF KNOWN, SEE 37 C.F.R. § 1.5)

09/402,713

INTERNATIONAL APPLICATION NO

PCT/CA98/00346

INTERNATIONAL FILING DATE

April 9, 1998

PRIORITY DATE CLAIMED

April 10, 1997

TITLE OF INVENTION

PCA3, PCA3 GENES, AND METHODS OF USE

APPLICANT(S) FOR DO/EO/US

BUSSEMAKERS, Marion J. G.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☐ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 372(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:
 - a. Copy of Notification of Missing Requirements;
 - b. Certificate Under 37 C.F.R. § 3.73(b), executed on behalf of University Hospital Nijmegen, with copy of Assignment attached;
 - c. Power of Attorney From Assignee With Delegation, executed on behalf of University Hospital Nijmegen;
 - d. Statement Claiming Small Entity Status-Nonprofit Organization, executed on behalf of University Hospital Nijmegen;
 - e. Statement Claiming Small Entity Status-Small Business Concern, executed on behalf of Diagnostics Inc.;
 - f. Paper and computer readable copies of Substitute Sequence Listing.;
 - g. Petition For Extension of Time Under 37 C.F.R. § 1.136(a)(1) (in duplicate); and
 - h. Communication Regarding Small Entity Status.

06/15/2000 PVOLPE 00000042 09402713

01 FC:228

925.00 OP

U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.50) 09/402,713		INTERNATIONAL APPLICATION NO. PCT/CA98/00346		ATTORNEY'S DOCKET NUMBER 1619.0020001/SRL/TBB	
17. <input checked="" type="checkbox"/> The following fees are submitted:				CALCULATIONS PTO USE ONLY	
Basic National Fee (37 CFR 1.492(a)(1)-(5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO \$970.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$840.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$690.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$670.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) \$ 96.00 ENTER APPROPRIATE BASIC FEE AMOUNT =				\$ -0-	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$ -0-	
Claims	Number Filed	Number Extra	Rate		
Total Claims	- 20 =		X \$18.00	\$ -0-	
Independent Claims	- 3 =		X \$78.00	\$ -0-	
Multiple dependent claim(s) (if applicable)			+ \$260.00	\$ -0-	
TOTAL OF ABOVE CALCULATIONS =				\$ -0-	
Reduction of ½ for filing by small entity, if applicable. A Small Entity Statement must be filed. (Note 37 CFR 1.9, 1.27, 1.28)				\$ -0-	
SUBTOTAL =				\$ -0-	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$ -0-	
TOTAL NATIONAL FEE =				\$	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$ 40.00	
TOTAL FEES ENCLOSED =				\$ 965.00*	
*Includes \$925.00 for extension for response within fifth month (37 C.F.R. § 1.17(a)(5)).				Amount to be refunded:	\$
				charged:	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$965.00 to cover the above fees is enclosed (includes \$925.00 extension fee).					
b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.					
c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0036. A duplicate copy of this sheet is enclosed.					
NOTE: Where an appropriate time limit Under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO: STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 New York Avenue, NW, Suite 600 Washington, D.C. 20005-3934					
				SIGNATURE Steven R. Ludwig NAME	DATE 6/13/00
				REGISTRATION NUMBER 36,203	



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: ASSISTANT COMMISSIONER FOR PATENTS
Box PCT
Washington, D.C. 20231

09/402713

U.S. APPLICATION NO. 09/402,713 FIRST NAMED APPLICANT BUSSEMAKERS ATTY. DOCKET NO. 1619.0020001

INTERNATIONAL APPLICATION NO.

PCT/CA98/00346

I.A. FILING DATE

PRIORITY DATE

04/09/98

04/10/97

DATE MAILED:

12/13/99

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

1. The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as

- ☐ a Designated Office (37 CFR 1.494),
☐ an Elected Office (37 CFR 1.495):

☒ U.S. Basic National Fee.

☐ Copy of the international application in:

- ☐ a non-English language.
☐ English.

☐ Translation of the international application into English.

☐ Oath or Declaration of inventors(s) for DO/EO/US.

☐ Copy of Article 19 amendments.

☐ Translation of Article 19 amendments into English.

☒ The International Preliminary Examination Report in English and its Annexes, if any.

☐ Translation of Annexes to the International Preliminary Examination Report into English.

☐ Preliminary amendment(s) filed _____ and _____.

☐ Information Disclosure Statement(s) filed _____ and _____.

☐ Assignment document.

☐ Power of Attorney and/or Change of Address.

☐ Substitute specification filed _____.

☐ Statement Claiming Small Entity Status.

☒ Priority Document.

☒ Copy of the International Search Report ☒ and copies of the references cited therein.

☐ Other: _____.

2. The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

☐ a. Translation of the application into English. Note a processing fee will be required if submitted later than the appropriate 20 or 30 months from the priority date.

☐ The current translation is defective for the reasons indicated on the attached Notice of Defective Translation.

☐ b. Processing fee for providing the translation of the application and/or the Annexes later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(f)).

☒ c. Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.

☐ The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.

☐ d. Surcharge for providing the oath or declaration later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(e)). **Prepaid.**

3. Additional claim fees of \$ _____ as a ☐ large entity ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due (37 CFR 1.492(g)). See attached PTO-875.

ALL OF THE ITEMS SET FORTH IN 2(a)-2(d) AND 3 ABOVE MUST BE SUBMITTED WITHIN ONE MONTH FROM THE DATE OF THIS NOTICE OR BY ☐ 21 OR ☐ 31 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

4. Translation of the Annexes **MUST** be submitted no later than the time period set above or the annexes will be cancelled. Note processing fee will be required if submitted later than 30 months from the priority date.

5. ☐ The Article 19 amendments are cancelled since a translation was not provided by the appropriate 20 (37 CFR 1.494(d)) or 30 (37 CFR 1.495(d)) months from the priority date.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

A copy of this notice *MUST* be returned with this response.

Enclosed: ☐ PCT/DO/EO/917 ☐ Notice of Defective Translation

☐ PTO-875

FORM PCT/DO/EO/905 (December 1997)

Stamp: **RECEIVED**
DEC 15 1999
STERNE, KESSLER, GOLDSTEIN & FOX PLLC
SPL
TBB
12/16/99
DOCKETED
decl - January 13, 2000
Stat Bar - June 13, 2000
Stamp: **Checked/Amended SA**
Telephone: (703) National Stage Processing
(703) 305-3659

PTO/PCT Rec'd 13 JUN 2000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Marion J. G. Bussemakers

Appl. No. 09/402,713 (U.S. National
Phase of PCT/CA98/00346)

Filed: (Int'l Filing Date: April 9, 1998)

For: **PCA3, PCA3 Genes, and Methods
of Use**

Art Unit: (To be assigned)

Examiner: (To be assigned)

Atty. Docket: 1619.0020001/SRL/TBB

Communication Regarding Small Entity Status

Commissioner for Patents
Box PCT
Washington, D.C. 20231

Sir:

Small entity status was established in good faith on December 8, 1999, by filing a small entity form executed on behalf of Diagnocure Inc. Small entity status was applicable for this case on December 8, 1999, and small entity status remains applicable for this case.

On February 17, 2000, the undersigned attorney was informed that another entity, University Hospital Neijmegen, also has rights in the invention. This other entity also qualifies as a small entity.

Submitted herewith are the appropriate small entity forms executed on behalf of each entity with an interest in the invention.

At the time Applicants established small entity status on December 9, 1999, Applicants also filed a request for a refund of one-half of the fees paid as a large entity on October 8, 1999. A credit to our Deposit Account No. 19-0036 in the amount of \$590.00 was made in February 2000. The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency,

or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this
Communication is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Steven R. Ludwig
Attorney for Applicant
Registration No. 36,203

Date: June 13, 2000

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600